

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL
COMPANY LIMITED et al.,

Plaintiffs,

v.

NORWICH PHARMACEUTICALS, INC.
et al.,

Defendants.

Civil Action No. 20-8966 (SRC)

OPINION & ORDER

CHESLER, District Judge

This matter comes before the Court on two motions: 1) the motion to extend the 30-month stay of FDA approval by Plaintiffs Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals U.S.A. Inc. (collectively, “Takeda”); and 2) the appeal of Magistrate Judge Waldor’s text Order, Docket Entry No. 269, entered June 9, 2022 (hereinafter, the “Vacate Order”), by Defendant Norwich Pharmaceuticals, Inc. (“Norwich.”)

As to the motion to extend the 30-month stay, the Court will reserve decision at this time. Under the Scheduling Order presently in effect, this Court expects to be able to resolve this case before the expiration of the 30-month stay, which would render the motion moot.

As to Norwich’s appeal of the Magistrate Judge’s Vacate Order, the Vacate Order will be affirmed. In brief, the Vacate Order vacated the Magistrate Judge’s Amended Scheduling Order, Docket Entry No. 234, which had been the subject of an appeal to the district court, filed by Takeda, and subsequently withdrawn. The Vacate Order states:

TEXT ORDER: The Court will vacate DE 234 scheduling order as upon reconsideration and as discussed the time frames are inadequate with respect to the trial date. The Court will administrative terminate DE 244 as this Court treated that motion as a Motion for Reconsideration. The Court will vacate DE 242 for the reasons discussed. Parties will meet and confer on issues discussed. The Court will reconvene the conference on July 15, 2022 via Zoom @ 3pm.. So Ordered by Magistrate Judge Cathy L. Waldor on 6/9/22.

Norwich argues that the Vacate Order is contrary to law. A Magistrate Judge's non-dispositive order may be set aside if it is clearly erroneous or contrary to law. 28 U.S.C. § 636(b)(1)(A); L. Civ. R. 72.1(c)(1)(A). In this District, when "the magistrate has ruled on a non-dispositive matter such as a discovery motion, his or her ruling is entitled to great deference and is reversible only for abuse of discretion." Kresefsky v. Panasonic Communs. & Sys. Co., 169 F.R.D. 54, 64 (D.N.J. 1996). The burden is on the party filing the appeal to demonstrate that the standard for modifying or setting aside the magistrate judge's ruling has been met. Cardona v. Gen. Motors Corp., 942 F. Supp. 968, 971 (D.N.J. 1996).

Norwich fails to persuade this Court that the Vacate Order is clearly erroneous or contrary to law, for several reasons. First and foremost, although the motion brief is titled as if Defendant challenges the text order which vacated the Amended Scheduling Order, the brief's arguments do not focus on the decision to vacate the Amended Scheduling Order. Instead, the opening brief raises a diffuse set of issues based on events *subsequent* to the Vacate Order. Thus, Defendant's opening brief does not focus on the legal validity of the Vacate Order itself, but on what happened afterwards as the Magistrate Judge worked to create a new, expedited schedule for the case. Norwich mixes together the decision to vacate the old schedule with subsequent decisions that modified and expedited the schedule.

Defendant contends that, *after* deciding to vacate the Amended Scheduling Order, the Magistrate Judge:

present[ed] Norwich with the Hobson's choice of keeping the January 2023 trial date and extending its commitment not to launch or accepting a trial date four months before patent expiration. Simply put, asking Norwich to extend its commitment not to launch was contrary to law.

(Def.'s Br. 7-8.) In addition, Norwich argues that the other possibility, a trial date four months before patent expiration, violates Federal Rule of Civil Procedure 16(b)(4), which states: "A schedule may be modified only for good cause and with the judge's consent." Norwich contends that Takeda failed to show good cause to modify the case schedule.

This Court thus distinguishes two issues that Norwich mixes together. The first is the nominal subject of this motion, the Magistrate Judge's Vacate Order, which vacated the Amended Scheduling Order. The Amended Scheduling Order had set a trial date of January 30, 2023. The Vacate Order merely vacated that schedule. On the day that Norwich filed the instant appeal, June 21, 2022, no new trial date had been set. It was not until July 7, 2022 that the Magistrate Judge issued a new scheduling order, first setting trial on November 28, 2022, then modifying the date to November 7 and 8, 2022. The second issue, then, concerns the new expedited case schedule. Although Norwich has not properly raised this issue on this motion – since the expedited schedule was not in place when Norwich filed its opening brief –, this Court will nonetheless address the issue of the expedited trial date as well.

There is no dispute that the Magistrate Judge issued the Vacate Order because the Amended Scheduling Order scheduled trial for a date after the end of the 30-month stay of FDA approval, December 5, 2022. Norwich has made no showing that the Magistrate Judge lacked the authority to issue the Vacate Order, or that its issuance was clearly erroneous or contrary to

law.¹ To the contrary, this Court finds that the Magistrate Judge acted appropriately in vacating a schedule with a trial date after the end of the 30-month stay and less than one month before the expiration of the patents at issue.

The Magistrate Judge’s issuance of the Vacate Order served the interests of justice by enabling a speedier resolution to this case. Rule 1 makes clear that every party before the Court is entitled to a speedy resolution; the Federal Rules of Civil Procedure “should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.” The Federal Circuit has held: “In the case of drugs that enjoy patent protection, the Hatch-Waxman Act creates a mechanism that allows for *prompt* judicial determination of whether the ANDA applicant’s drug or method of using the drug infringes a valid patent.” Bayer Schering Pharma AG & Bayer HealthCare Pharm., Inc. v. Lupin, Ltd., 676 F.3d 1316, 1318 (Fed. Cir. 2012) (*italics added*). The Magistrate Judge’s issuance of the Vacate Order advanced the cause of prompt judicial determination.

¹ “[D]istrict courts have the inherent authority to manage their dockets and courtrooms with a view toward the efficient and expedient resolution of cases.” Dietz v. Bouldin, 579 U.S. 40, 47 (2016). Furthermore, L. Pat. R. 1.3 states:

The Court may modify the obligations or deadlines set forth in these Local Patent Rules based on the circumstances of any particular case, including, without limitation, the simplicity or complexity of the case as shown by the patents, claims, products, or parties involved. Such modifications shall, in most cases, be made at the initial Scheduling Conference, but may be made at other times by the Court *sua sponte* or upon a showing of good cause.

The Magistrate Judge’s issuance of the Vacate Order was a proper exercise of her authority under L. Pat. R. 1.3.

Nor has Norwich made any showing that either the Vacate Order itself, or the subsequent decisions to expedite the case schedule, has worked unfair prejudice. The only actual impact of the expedited schedule that Norwich points to is that various pre-trial deadlines will need to be made earlier: the parties are indeed likely to have a period of time in which they will need to work harder to meet those deadlines, as they prepare the case for trial, but Norwich has not persuaded the Court that this burdens one side more than the other. The Court has confidence that the capable attorneys representing both sides have the ability to prepare for an earlier trial. The benefit that results from working toward earlier deadlines is a speedier resolution of the dispute, which benefits both parties. The Court further believes that accelerating the schedule will help the parties focus on the most critical issues as they streamline their cases for trial, progressing toward the prompt judicial determination envisioned by the Hatch-Waxman Act.

Norwich has not persuaded this Court that the Vacate Order is clearly erroneous or contrary to law, nor an abuse of discretion. Defendant's appeal of the Vacate Order will be denied, and the Vacate Order will be affirmed.

For these reasons,

IT IS on this 14th day of July, 2022

ORDERED that Defendant's appeal of the Magistrate Judge's Vacate Order (Docket Entry No. 278) is **DENIED**; and it is further

ORDERED that the Vacate Order (Docket Entry No. 269) is **AFFIRMED**; and it is further

ORDERED that decision on Plaintiff's motion to extend the 30-month stay of FDA approval (Docket Entry No. 275) is **RESERVED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge